APR 0 4 2014

510(k) Summary
NordicNeuroLab AS
nordicBrainEx Software

Submitter: NordicNeuroLab AS
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Primary Contact: Chandana Gurung Bhandari (chandana@nordicneurolab.com)

Proprietary Name:	nordicBrainEx Software
Device Common Name:	PACS
Device:	System, image processing, radiological
Classification Name:	Picture archiving and communication system
Classification Regulation:	892.2050
Class:	II
Panel:	Radiology
Product Code:	LLZ

Predicate device name: Nordic Image Control and Evaluation (nordicICE) Software K090546

Device Description

The nordicBrainEx Software is a post-processing application for dynamic MRI data developed with focus on ease of use and high-performance on a standard Windows workstation. The software provides comprehensive functionality for dynamic image analysis and visualization of MRI data, where signal changes over time are analyzed to determine various modality dependent functional parameters. The following algorithms provide the main functional analyses of the application.

- BOLD: BOLD fMRI analysis is used to highlight small magnetic susceptibility changes in the human brain in areas with altered blood-flow resulting from neuronal activity.
- DTI: Diffusion analysis is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. Fiber tracking utilizes the directional dependency of the diffusion to display the white matter structure in the brain.
- DSC: Calculations of perfusion related parameters that provide information about the blood vessel structure and characteristics. Examples of such maps are blood volume, blood flow, time to peak, mean transit time and leakage.

In addition to these specific functional analyses, the application also provides general visualization tools, a database for data handling, and a reporting feature. This is to ensure that the workflow of the application is optimized to ensure efficiency and high throughput in a clinical environment.

Intended Use

nordicBrainEx is an advanced visualization and processing software, with specific focus on providing algorithms designed to analyze functional MR data of the brain. The software runs on a standard "off-the-shelf" PC workstation and can be used with data and images acquired through DICOM compliant imaging devices and modalities.

The software is intended to be used by medical personnel, such as radiologists or medical technicians, trained in the methods provided by the application. In order to best accommodate this group of users, it is specifically designed to have an easy to use and streamlined workflow, as well as an intuitive graphical user interface.

Indications For Use

nordicBrainEx provides analysis and visualization capabilities of dynamic MRI data of the brain, presenting the derived properties and parameters in a clinically useful context.

The indications for use of the predicate device, nordicICE, is formulated in a more general way with focus on delivering specific functionality to a clinical environment. However, since those functionalities are the same as those in nordicBrainEx the more specific indications of nordicBrainEx are considered to be substantially equivalent to those of nordicICE. See SE discussion for more details.

Technological Characteristics and Substantial Equivalence

The nordicBrainEx Software is substantially equivalent to the nordicICE Software (K090546) in technological characteristics and operational characteristics.

	nordicBrainEx	**nordicICE**
Development framework	Embarcadero C++ Builder XE2	Embarcadero C++ Builder 2010
Programming language	C++	C++
Operating environment	"Off-the-shelf" windows PC workstation	"Off-the-shelf" windows PC workstation
Input data	DICOM compliant MR data	DICOM compliant MR data RAW Analyze Nifti
General functionality	2D MPR visualization 3D Visualization Volumes of interest	2D MPR visualization 3D Visualization Regions of interest

	Measurement tools DICOM compliant node Reporting tool	Measurement tools DICOM compliant node
Dynamic analyses	BOLD DTI DSC	BOLD DWI DTI DSC DCE

More details can be found in the substantial equivalence discussion.

The rationale for determining the substantial equivalence between nordicBrainEx and nordicICE is based on the defined intended use, indications for use, and the technical and operational characteristics of the two applications. To verify that nordicBrainEx fulfils the defined characteristics and requirements, it has been subject to extensive in-house testing (see section below). The successful completion of said tests verifies the claimed characteristics of nordicBrainEx, and thus supports the determination of substantial equivalence.

Performance Testing

Prospectively defined verification and validation activities for the nordicBrainEx Software assure that the nordicBrainEx Software meets design and performance specifications as well as user needs when operated according to the operating instructions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

NordicNeuroLab AS
% Ms. Chandana Gurung Bhandari
VP Quality
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N-5009 Bergen
NORWAY

April 4, 2014

Re: K133910
Trade/Device Name: nordicBrainEx v 2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 21, 2014
Received: March 26, 2014

Dear Ms. Bhandari:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K133910

Device Name: nordicBrainEx Software

Indications for Use:

nordicBrainEx provides analysis and visualization capabilities of dynamic MRI data of the brain, presenting the derived properties and parameters in a clinically useful context.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael D. O'Hara

(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) _____K133910_____